THE CENTER FOR
FOOD SAFETY

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8 May 2000

Commissioner Jane Henney
Food and Drug Administration
Parklawn Building, Room 1471
5600 Fishers Lane
Rockville, MD 20857

CC: Docket No. 99P-0033
FDA Dockets Management Branch
HFA -305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Henney:

Pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. S 553(e), and the FDA implementing regulations, the Humane Farming Association, the Center for Food Safety and others petitioned your office on January 7, 1999, to take action regarding, *inter alia*, the potential human and animal health impacts, including transmissible spongiform encephalopathies (TSEs) associated with the current FDA animal feed regulations found at 21 C.F.R. § 589.2000. See FDA Docket No. 99P-0033. More specifically, the agency has been requested to initiate new rulemaking to close loopholes in current animal feed regulations that create risks of TSE transmission in animals and pose a significant health threat to the public.

Since the filing of the petition well over a year ago, your office has failed to take any action concerning the issues presented by the petitioners. Unfortunately, the issues presented in the petition are more salient than ever. A fatal TSE disease called 'chronic wasting disease' or CWD is occurring at epidemic levels in deer and elk in Western states and on game farms. This TSE may already be claiming human lives as suggested by the alarming appearance of unusually young victims of Creutzfeldt-Jakob disease or CJD, a human form of TSE. Some scientists suspect that CWD emerged when a strain of scrapie, a TSE widespread in US sheep, transmitted to deer and elk. Now, CWD may have transmitted from deer and elk into humans as CJD.

Our original petition cited the case of Doug McEwen of Utah, who is now dead of CJD, as an example of the potential human health threat posed by the continued lax FDA animal feeding regulations . Since the filing of our petition news reports have mentioned other young, confirmed and suspected victims.

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For example: Jay Dee Whitlock II, age 28, of Miami, Oklahoma died of CJD less than a month ago on April 7, 2000. Mr. Whitlock was an avid deer hunter and consumer of venison.' Jim Koepke, age 39, died of CJD on February 6, 1999, and was also a consumer of deer and elk.

We can look at Great Britain to see the massive human and animal health, economic and environmental disaster caused by the British TSE dubbed 'mad cow disease,' a bovine spongiform encephalopathy or BSE. The current human death toll from BSE is 53 and rising. In the decades ahead some scientists suspect it could kill hundreds of thousands of people.

It was the emergence of a "new variant CJD" or nvCJD in unusually young victims that led to the current scientific consensus that mad cow disease is killing humans. Thus, the appearance of unusually young CJD victims in the US is a very disconcerting development in light of the widespread occurrence of US sheep scrapie and the emergence of CWD at epidemic levels in deer and elk.

Furthermore, given the situation in Great Britain, it may be just months or a couple years before cases of nvCJD appear in the US among people who lived in or visited Britain in the 1980s. This event, no matter how it is downplayed by industry interests, will emphasize the inadequacies of current US regulations and our own dilemmas with chronic wasting disease and sheep scrapie.

On August 5, 1999, petitioners reiterated the request that the agency answer their legal petition. In correspondence, FDA Director of the Center for Veterinary Medicine Stephen Sundlof stated that the agency required more time to respond. The time afforded the agency since Dr. Sundlof's response has been more than adequate to facilitate the agency's answer to the petition. And, as of November 1999, well over 250 members of the public have written in support of the petition's request.

Given the mounting evidence in favor of taking the most precautionary stance toward our own animal feeding regulations, in refusing to act the FDA continues to deny petitioners and these members of the public relief at the agency level and is a constructive denial of the petitioner's request. As such, petitioners intend to pursue other avenues, including judicial review, in order to assure that the agency responds to the issues raised by the petitioners.

Indeed, the agency inaction in this matter is subject to judicial review. Under the APA "agency action" is defined to include "the whole or part of an agency rule, order, license, sanction, relief, or the equivalent denial thereof, or failure to act" and gives courts the power to "compel agency action unlawfully withheld or unreasonably delayed." Thus, the APA authorizes courts to review agency decisions to refrain from taking action. When administrative inaction has precisely the same impact on the rights of the parties as denial of relief, an agency cannot preclude judicial review by casting its decision in the form of inaction rather than in the form of an order denying relief.

In addition, the agency's inaction is violative of established agency regulations. The FDA has established regulations in which a reasonable period for agency response to citizen petitions can be no more than 180 days. Regulations which are promulgated by an administrative agency in carrying out it statutory mandate can also provide standards for judicial review of agency action. Such self-imposed constraints may supply the "law to apply" to overcome the judicial presumption against reviewing administrative inaction. Thus, the agency must act in a "prompt" manner or be subject to further action. The agency's

delay in answering the current petition amounts to a refusal to act, with sufficient finality and ripeness to permit judicial review.

Furthermore, petitioners remind the FDA that excessive and unreasonable delay in addressing matters brought to its attention by the public saps the public confidence in an agency's ability to discharge its responsibilities and creates uncertainty for the parties, who must incorporate the potential effect of possible agency decision making in the future.

Petitioners request the agency to respond to the aforementioned petition within thirty (30) calendar days. In the absence of an affirmative response, the petitioners will be compelled to consider litigation in order to achieve the full and complete action required to address this violation of federal law.

On behalf of the petitioners,

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Legal Director

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